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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,086	09/21/2001	Douglas D. Ross	028754-039	6592

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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/961,086	ROSS ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *5-7 and 13-15* is/are pending in the application.

4a) Of the above claim(s) *13-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/13/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Amendment filed September 19, 2005 in response to the Office Action of June 17, 2005 is acknowledged and has been entered. Claims 5-7, 13-15 are amended. Claims 5-7 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are being maintained:

Claim Rejections - 35 USC 103

4. Claims 5-7 remain rejected under 35 USC 103 for the reasons previously set forth in the action mailed June 17, 2005, pages 5-8.

Applicant argues that taken together Purnelle and Harlow or Kirby and Harlow fail to meet the requirements for a *prima facie* case of obviousness because they do not suggest any motivation for one skilled in the art to modify or combine the teachings disclosed therein. Further, given the teachings of the prior art references, one would not have a reasonable expectation of success to modify such disclosures to make the present invention. Finally, the cited references fail to teach or suggest all of the limitations of the claims. The arguments have been considered but have not been found persuasive for the reasons set forth below.

In particular, Applicant argues that Purnelle merely discloses a sequence listing and fails to teach monoclonal or polyclonal antibodies and further, Harlow does not provide the motivation necessary under the *prima facie* obviousness analysis to bind antibodies to SEQ ID NO:1 and Applicant cites *In re Dow Chemical Co* to support the contention that given the above the *prima facie* case of obviousness cannot be satisfied.

The argument has been considered but has not been found persuasive because the claims are drawn to an isolated antibody which binds to SEQ ID NO:1.

However, motivation to bind monoclonal or polyclonal antibodies to SEQ ID NO:1, in particular, is not required because the claims simply require antibodies that bind to SEQ ID NO:1. Nothing is the claims requires that the antibodies selectively bind to any particular epitope on SEQ ID NO:1. Thus any antibody that will bind to any epitope found in SEQ ID NO:1 meets the limitations of the claims. Further, given the findings of the court in *Ex parte Ehrlich, Ex parte Sugimoto*, as previously set forth the claimed monoclonal antibodies are obvious. Finally, given the teachings of Harlow in combination with Purnelle et al, the claimed polyclonal antibodies are obvious.

Applicant argues that the present invention does not identify anywhere in the disclosure any particular point of novelty of SEQ ID NO:1 that would suggest to the skilled artisan that SEQ ID NO:1 would bind to monoclonal or polyclonal antibodies in the same manner as the sequences disclosed in Purnelle. Applicant again cites *Dow Chemical Co* and argues that similar to the fact pattern in *Dow Chemical Co*, none of the references suggests any process that could be used successfully to produce this product having the desired properties.

The argument has been considered but has not been found persuasive because Applicant's arguments validate Examiner's findings of obviousness drawn to the claimed polyclonal and monoclonal antibodies since Applicant admits on the record that the present invention does not identify any particular point of novelty of SEQ ID NO:1 thus any antibody, monoclonal or polyclonal, that binds to any epitope found on SEQ ID NO:1 meets the limitations of the claims. Again, given the findings of the court in *Ex parte Ehrlich, Ex parte Sugimoto*, and the teachings of Harlow, regardless of whether or not the obvious antibodies of the combined prior art reference was produced specifically to bind to SEQ ID NO:1, at least a

subset of the obvious antibodies produced against the prior art polypeptide will bind to SEQ ID NO:1 for the reasons set forth previously and above. The claimed antibodies themselves are obvious and one would have a reasonable expectation of success in producing the obvious antibodies given the identity of the Purnelle et al reference polypeptide and SEQ ID NO:1.

Applicant argues that the Board found that where a prior art reference discloses residues with 86% to 98% identity with the claimed subject matter, the Board has still found the invention nonobvious and patentable over the prior art and cites *Ex Parte Kamboj et al.*

The argument has been considered but has not been found persuasive because Applicant has not disclosed any nexus between the cited case-law and the instant case. Applicant has not disclosed whether *Ex Parte Kamboj et al* is drawn to the antibody arts, whether *Ex Parte Kamboj et al* is drawn to epitopes or whether it is drawn to the non-obviousness of one polypeptide over another polypeptide which is homologous to it, which is an art that is not analogous to the instant invention. Thus, the findings of the Board cannot be here evaluated.

Applicant points to a USPTO publication entitled "Trilateral Project B3b: Mutual understanding in search and examination; Comparative study on biotechnology patent practices" and points in particular to Case 5 described therein. Applicant reviews Case 5 and states that in Case 5, a similarity search was performed and it was found that the claimed polynucleotides showed 40-50% identity with the prior art documents. In the analysis of Case 5, the Office found that the prior art did not render the invention obvious despite the 40-50% identity of the two polypeptides. Applicant argues that a mere 30% identity, combined with a lack of teaching, disclosure or suggestion in the prior art references to make the

present invention, clearly establishes that the invention would be non-obvious to the skilled artisan.

The argument has been considered but has not been found persuasive because the claims are drawn to antibodies which bind epitopes comprised in SEQ ID NO:1 and not to polypeptides homologous to SEQ ID NO:1, therefore the analysis of Case 5 is not relevant to the instant rejection. As previously set forth, given that neither the claims nor the specification point to any particular amino acid sequence to which the antibodies must be directed, the claimed antibodies are obvious for the reasons of record.

Applicant reiterates the arguments set for above drawn to the Kirby and Harlow references. The arguments have been considered but have not been found persuasive for the reasons set forth above.

Applicant argues that the fact that a general process can be conceived in advance for preparing an undefined sequence does not mean that a specifically claimed sequence could have been precisely envisioned and therefore obvious. The argument has been considered but has not been found persuasive because Applicant is not claiming a specifically claimed sequence, but rather is claiming antibodies to a specifically claimed sequence which are obvious for the reasons of record.

Applicant argues that absent a specific teaching in the cited references that this particular SEQ ID NO:1 would bind similarly as the sequence as disclosed in Purnelle or Kirby to a monoclonal or polyclonal antibody, the references fail to teach the present invention and therefore cannot support a rejection under 35 USC 103.

The argument has been considered but has not been found persuasive because, as previously set forth, given the sequence identity of Purnelle or Kirby to SEQ ID NO:1, one would have a reasonable expectation that the polypeptides of Purnelle or Kirby comprise epitopes in common with SEQ ID NO:1 and therefore one would have a reasonable expectation of success in producing both monoclonal and polyclonal antibodies that bind to SEQ ID NO:1. For the reasons set forth previously and above, the claimed invention is obvious over the cited references.

Applicant argues that because the disclosures present in the cited references could not have led the skilled artisan to have isolated this particular sequence of SEQ ID NO:1, with these particular amino acids as claimed, the *prima facie* case of obviousness cannot be satisfied.

The argument has been considered but has not been found persuasive because the claims do not require the isolation of SEQ ID NO:1 or that the antibody be selective for SEQ ID NO:1, the claims require only that the antibodies bind to SEQ ID NO:1 and for the reasons set forth previously and above, the antibodies of the combined references make obvious the claimed invention.

Applicant argues that the cited references fail to contain any motivation to modify the references, fail to disclose each and every one of the elements in the presently claimed invention and lack any reasonable expectation of success.

The argument has been considered but has not been found persuasive. Although it is true to the cited references fail to contain any motivation to modify the references, modification of the references is not required to produce the antibodies claimed or to make those antibodies obvious. Given the sequence identity of Purnelle or Kirby to SEQ ID NO:1, one would have a reasonable expectation that the polypeptides of Purnelle or Kirby comprise epitopes in

common with SEQ ID NO:1 and therefore one would have a reasonable expectation of success in producing at least a subset of both monoclonal and polyclonal antibodies that bind to SEQ ID NO:1 using the prior art polypeptides as antigens. Contrary to Applicant's arguments, the prior art references in combination disclose each and every one of the elements in the presently claimed invention and given the conventional nature of the antibody art, there is a reasonable expectation of success in producing the claimed antibodies.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

5. All other objections and rejections recited in the paper mailed June 17, 2005 are hereby withdrawn.

6. No claims allowed.

7. **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

(571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787 The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
November 2, 2005